SECTION 2

LABORATORY SERVICES

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1 GENERAL POLICY

Laboratory services are specialty medical services essential to the physician scope of service, ordered and provided by or under the direction or supervision of a physician or other licensed practitioner of the healing arts within the scope of practice as defined by state law. Laboratory services provide examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, assessment, or treatment of any disease or impairment of the health of human beings. Laboratory examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Laboratories, whether in a physician's office or another organized facility, are limited in the kinds of specialty or subspecialty services they can provide based on available equipment and capability to provide an appropriate, competent level of laboratory service. The Department of Health must approve a facility to operate as a laboratory, and laboratories must satisfy the requirements of the federal Clinical Laboratory Improvement Amendments (CLIA) to participate in the Medicare and Medicaid program. The purpose of CLIA is to uniformly ensure the quality and reliability of medical tests performed by all laboratories which test human specimens. CLIA as codified at 42 CFR Part 493 provides authority for review and monitoring of facilities operating as laboratories.

Laboratory services are authorized by Sections 1861(e) and (j), the sentence following Section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and Section 353 of the Public Health Service Act.

For information on obtaining CLIA certification, contact your state laboratory licensing agency. In Utah, contact the Bureau of Laboratory Improvement.

The address is:
Bureau of Laboratory Improvement
46 North Medical Drive
Salt Lake City UT 84113

The telephone numbers are (801) 584-8471, 584-8472 or 584-8295.

1 - 1 Clients Enrolled in a Managed Care Plan

A Medicaid client enrolled in a managed care plan, such as a health maintenance organization (HMO) or Prepaid Mental Health Plan (PMHP), must receive all health care services through that plan. Refer to SECTION 1, Chapter 5, Verifying Eligibility, for information about how to verify a client's enrollment in a plan. For more information about managed health care plans, please refer to SECTION 1, Chapter 4, Managed Care Plans. Each plan may offer more benefits and/or fewer restrictions than the Medicaid scope of benefits explained in this section of the provider manual. Each plan specifies services which are covered, those which require prior authorization, the process to request authorization and the conditions for authorization.

All questions concerning services covered by or payment from a managed care plan must be directed to the appropriate plan. Medicaid does NOT process prior authorization requests for services to be provided to a Medicaid client who is enrolled in a capitated managed care plan when the services are included in the contract with the plan. Providers requesting prior authorization for services for a client enrolled in a managed care plan will be referred to that plan.

A list of HMOs and PMHPs with which Medicaid has a contract to provide health care services is included as an attachment to this provider manual. Please note that Medicaid staff make every effort to provide complete and accurate information on all inquiries as to a client's enrollment in a managed care plan. Because eligibility information as to which plan the patient must use is available to providers, a fee-for-service claim will not be paid even when information is given in error by Medicaid staff.

NOTE: SECTION 1 is available on the Internet at www.health.state.ut.us/medicaid/SECTION1.pdf

1 - 2 Clients NOT Enrolled in a Managed Care Plan (Fee-for-Service Clients)

Medicaid clients who are *not* enrolled in a managed care plan may receive services from any provider who accepts Medicaid. This provider manual explains the conditions of coverage for Medicaid fee-for-service clients.

1 - 3 Definitions

Definitions of terms used in multiple Medicaid programs are in SECTION 1, Chapter 13, *Definitions.* Definitions particular to rural health clinic services are below.

Approved State Laboratory Program

A licensure or other regulatory program for laboratories in a State, the requirements of which are imposed under State law, and the State Laboratory program has received HCFA approval.

Authorized Person

An individual authorized under State law to order tests or receive test results.

Bundling

The concept used by Medicare and adopted by Medicaid, to cover all inpatient hospital services by the DRG ---- use of hospital facilities, technical portion of clinical laboratory and radiology services, nursing, therapy services, medical social services, and other related services furnished by the hospital as part of the general accommodations for inpatient service.

Certificate of Compliance

A certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable condition level requirements.

Certificate of Provider Performed Microscopy (PPMP) Procedures

Certificate issued to a laboratory in which a physician, midlevel practitioner, or dentist performs no tests other than PPMP procedures, and if desired, waiver tests.

Certificate of Registration (Registration Certificate)

A certificate issued that enables the entity to conduct moderate or high complexity laboratory testing or both until the entity is determined to be in compliance through a survey by HCFA or its agent.

Certificate of Waiver

A certificate issued to a laboratory to perform only the waived tests.

Clinical Laboratory Improvement Amendments (CLIA)

The federal Health Care Financing Administration program which limits reimbursement for laboratory services based on the equipment and capability of the physician or laboratory to provide an appropriate, competent level of laboratory service.

Diagnostic Related Group (DRG)

The system established to recognize and reimburse for the resources used to treat a client with a specific diagnosis or medical need. The DRG weight, average length of stay (ALOS), and outlier threshold days are extracted from Utah Medicaid paid claims history files or from the U.S. Department of Health and Human Services, Health Care Financing Administration.

Inpatient

An individual admitted to a hospital and expected to remain for more than 24 hours to receive diagnostic, therapeutic, surgical and/or professional services. All services provided in the hospital, with the exception of professional services, are bundled under the DRG payment made for the service.

Kit All components of a test that are packaged together.

Laboratory

An approved facility that conducts the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

Midlevel Practitioner

A nurse practitioner or nurse midwife licensed to practice within the State.

Outpatient

An individual who receives professional services at a hospital for less than a 24 hour period.

Physician

An individual with a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine degree who is licensed by the State to practice medicine, or osteopathy or podiatry within the state where the laboratory is located.

Professional Component

That part of laboratory or radiology service that may be provided only by a physician capable of analyzing a procedure or service and providing a written report.

Services

The types of medical assistance specified in Sections 1905(a)(1) through 25 of the Social Security Act and interpreted in the 42 Code of Federal Regulations, Section 440.

Technical Component

That part of laboratory service necessary to secure a specimen and prepare it for analysis, or to take an x-ray and prepare it for reading and interpretation. (In some cases, the technical portion of the service is all that is required. No professional service is necessary.)

2 COVERED SERVICES

Medically necessary diagnostic and therapeutic services, appropriate for the adequate diagnosis or treatment of a client's illness, ordered and supervised by a physician or other practitioner of the healing arts are covered services.

Services must be consistent with principles of efficiency, economy and quality of care. Some limitations apply.

A. Laboratory tests are essential to monitor the progress of dialysis patients. The following list of tests and frequencies constitute the level and types of routine laboratory tests that are covered under the Composite Payment Rate. Other tests are considered nonroutine and can be billed separately. Routine tests at greater frequencies must include medical justification. This schedule is based upon recommendations from HCFA for Medicare patients eligible for ESRD services.

The routinely covered regimen includes the following tests.

Each Dialysis Session

All hematocrit or hemoglobin and clotting time tests furnished incident to the dialysis treatment.

Weekly

Prothrombin time for patients on anticoagulant therapy
Serum Creatinine
BUN (Limited to 13 per quarter)

Monthly

CBC
Serum Calcium
Serum Potassium
Serum Chloride
Serum Bicarbonate
Serum Phosphorous
Total Protein
Serum Albumin
Alkaline Phospatase
AST, SGOT
LDH

Every Three Months

Serum Aluminum
Serum Ferritin

B. Hepatitis B Surface Antigen (HbsAg) and Anti-HBs for hepatitis B are covered when patients first enter a dialysis facility. Coverage of future testing in these patients depends on their serologic status and on whether they have been successfully immunized against hepatitis B virus.

The following table summarizes the frequency of serologic surveillance for hepatitis B. Tests furnished according to this table do not require additional documentation and are paid separately because payment for maintenance dialysis treatments does not take them into account.

Frequency of Screening		
Vaccination and Serologic Status	**HbsAG Patients**	**Anti-HBs Patients**
Unvaccinated		
Susceptible	Monthly	Semiannually
HbsAg Carrier	Annually	None
Anti-HBs- positive [1]	None	Annually
Vaccinated		
Anti-HBs- positive	None	Annually
Low Level or No Anti-HBs	Monthly	Semiannually
[1] At least 10 sample ration units by radioimmunoassay or positive by enzyme immunoassays.		

C. CPT code 80074, acute hepatitis panel, includes four other codes: 86709, 86705, 87340, and 86803. When three of the four codes are billed, they will be rebundled into the acute hepatitis panel code 80074 for payment.

This page reserved for future use.

3 LIMITATIONS

1. Laboratory services are limited to those tests identified by the Health Care Financing Administration for which the individual provider or laboratory is CLIA certified to provide, bill and receive Medicaid payment.

2. Clinical diagnostic laboratory tests sent by a physician from his office to an outside laboratory must be billed by the laboratory completing the service. The laboratory can not look to the physician for payment. Billing and payment must be direct.

3. Laboratory services performed by the admitting hospital or by an entity wholly owned or operated by the hospital within three days prior to the date of admission to the hospital are deemed to be inpatient services and must be covered under the DRG.

4. Use of observation of treatment room status is limited to cases where time is needed for evaluation, to establish a diagnosis or need for admission and must not be used to provide or bill for known outpatient diagnostic services or extended diagnostic testing.

5. Laboratory tests must be billed using the appropriate "panel" designation. The reimbursement amount for all tests billed separately for the same patient on the same date of service by the same provider may not exceed the reimbursement amount for the equivalent "bundled" CPT code, whether or not a particular laboratory has automated equipment. Inappropriately billed codes will either be denied or rebundled to the appropriate panel.

6. A specimen collection fee is limited only to specimens drawn in a physician's office under the supervision of a physician to be sent outside of the office for processing and only to specimens collected by venipuncture or catheterization.

7. Finger/heel/or ear sticks are limited only to infants under the age of two years by use of CPT code 36415. (Such service is not covered for adults.)

8. By federal regulation, Medicaid is prohibited from paying more for clinical diagnostic laboratory tests than allowed for the same tests by the Medicare fee schedule. The Medicare fee schedule is based on the HCPCS coding system, and specimen collection fee must be considered in payment amount. Accuracy is essential to assure correct reimbursement and payment of crossover claims

9. Individuals who do not meet United States residency requirements (undocumented), but who meet all other Medicaid eligibility criteria, are eligible only for "Emergency Services". (Information about the Emergency Services Program can be found in the Utah Medicaid Provider Manual, SECTION 1, GENERAL INFORMATION.)

4 NON-COVERED SERVICES

The services listed in this chapter are not covered by the Utah Medicaid Program.

A. Services rendered during a period the recipient was ineligible for Medicaid.

B. Services medically unnecessary or unreasonable

C. Services which fail to meet existing standards of professional practice, which are currently professionally unacceptable, or which are investigational or experimental in nature.

D. Services requiring prior authorization, but for which such authorization was not requested, was not obtained, or was denied.

E. Services, elective in nature, and requested or provided only because of the recipient's personal preference.

F. Services for which third party payors are primarily responsible, e.g., Medicare, private health insurance, liability insurance. Medicaid may make a partial payment up to the Medicaid maximum if limit has not been reached by third party.

G. Services fraudulently claimed.

H. Services which represent abuse or overuse.

I. Services rejected or disallowed by Medicare when the rejection was based on any of the reasons set forth above.

J. "Stat charges", based on after hours or emergency parameters are not covered. Any facility which is open and offers a 24 hour service would need to have appropriate services, including laboratory, available without additional billing.

K. Laboratory services related to services excluded as family planning services:
   1. Infertility studies
   2. In-vitro fertilization
   3. Artificial insemination
   4. Tests, services, and related charges for surrogate motherhood.
   5. Tests related to abortion, except as exclusively provided by federal regulation.

L. Paternity testing

M. A drawing fee is not covered for specimens collected at the laboratory. The collection of the specimen is considered an inherent part of processing the specimen and the resultant payment.

N. A travel allowance is not covered by Medicaid for a technician to go to a nursing facility or to the home of a homebound patient to collect a specimen. (The Deficit Reduction Act of 1984 allowed this exclusion providing such service had not been covered prior to this time.)

O. Billing for additional automated hemogram indices by use of codes 85029 and 85030 is excluded. Modern automated equipment provides a complete hemogram profile including indices as a matter of routine. Additional billing for indices is not necessary.

P. Anatomic pathology (postmortem examination) and all associated services are non covered Medicaid services.

5 BILLING

Laboratory procedures may be billed electronically or on paper, using the HCFA-1500 claim format. Instructions for completing a paper HCFA-1500 claim are included with this manual.

5 - 1 CLIA Certification Number

The CLIA certification number must be included on each HCFA-1500 Form, whether paper or electronic format, for any laboratory performing a test covered by CLIA.

5 - 2 Laboratory Services Billed Separately

Laboratory services must be billed separately from all other services billed on a HCFA-1500 Form for both UMAP and Medicaid clients.

5 - 3 Technical and Professional Component

When a CPT procedure code allows the same provider to bill for both the technical component and the porfessional component, it is necessary to bill two lines, Bill line one for the technical component, then bill the second line for the professional component, with modifier 26.

5 - 4 Modifiers

QW Qualified Waiver: Signifies that a test kit was used, which requires a Waiver CLIA certificate and is reimbursed at a lower fee. The kit must be billed by adding the modifier ‘QW’ to the appropriate HCPCS code.

26 Professional Component: When a physician component is reported separately, the service may be identified by adding the modifier ‘26' to the usual procedure number.

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